IN THE CLAIMS

- 1. (Currently Amended) A multi-lumen balloon radiation centering catheter assembly, comprising:
- a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen, the plurality of outer lumens integrally coupled with the central lumen so as to form the multi-lumen balloon with a continuous perimeter; and
- a catheter shaft disposed proximate to the balloon, the catheter shaft including an inner lumen longitudinally extending through at least a portion of the catheter shaft proximate the balloon and connected to the central lumen, the inner lumen adapted for receiving a radiation source lumen, the inner lumen further adapted for receiving a guidewire lumen for positioning the multi-lumen balloon radiation centering catheter within a body vessel, wherein the guidewire lumen extends lengthwise through one of the plurality of outer lumens, and wherein slideable seals are provided to seal both ends of the multi-lumen balloon where the guidewire is received.
- 2. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 1, wherein the inner lumen is further adapted for receiving a plurality of inflation lumens that are in fluid communication with the plurality of outer lumens to allow an inflation medium to enter and inflate the plurality of outer lumens so as to cause the radiation source lumen to be centered within a body vessel.
- (Original) The multi-lumen balloon radiation centering catheter assembly of claim
 wherein each outer lumen is inflatable to different inflation pressures.
 Page 2 of 36
 3764.P025

- 4. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 1, wherein the inner lumen serves as an inflation lumen for the plurality of outer lumens.
- 5. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 1, further comprising a catheter outer member coupled with the catheter shaft.
- 6. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 5, wherein the catheter outer member includes an outer member lumen extending through at least a portion of the catheter outer member and connected to the catheter shaft inner lumen, the outer member lumen adapted for receiving a inflation lumen that is in fluid communication with the plurality of outer lumens for inflating the multi-lumen balloon.
- 7. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 1, wherein the radiation source lumen extends lengthwise through the central lumen of the multi-lumen balloon.
- 8. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 7, wherein the plurality of outer lumens have a plurality of proximal ends and distal ends coupled with the radiation source lumen so as to form a balloon proximal seal and a balloon distal seal.

09/506,081 Page 3 of 36 3764.P025

- 9. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 8, wherein a balloon treatment area is formed between the balloon proximal seal and the balloon distal seal.
- 10. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 9, wherein the balloon treatment area has a fluted shape.
- 11. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 1, wherein the guidewire lumen extending lengthwise through one of the outer lumens of the multi-lumen balloon is a standard rapid exchange guidewire lumen.
- 12. (Original) The multi-lumen balloon radiation centering catheter of claim assembly 1, further comprising a soft tip coupled to a distal end of the guidewire lumen.
- Original) The multi-lumen balloon radiation centering catheter of claim assembly 8, further comprising a distal marker and a proximal marker coupled with the radiation source lumen and disposed within the balloon distal seal and the balloon proximal seal.
- 14. (Original) The multi-lumen balloon radiation centering catheter assembly of claim13, wherein the distal marker is part of a radiation source lumen plug.
- 15. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 1, further comprising a radiation source disposed within the radiation source lumen.

09/506,081 Page 4 of 36 3764.P025

- 16. (Original) The multi-lumen balloon radiation centering catheter assembly of claim15, wherein the radiation source comprises a gamma radiation-emitting radiation source.
- 17. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 15, wherein the radiation source comprises a beta radiation-emitting radiation source.
- 18. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 17, wherein the radiation source comprises phosphorous-32.
- 19. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 2, wherein when inflated and engaged with the body vessel, the plurality of outer lumens form straight longitudinal paths that allow for perfusion of blood past the multi-lumen balloon.
- 20. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 1, wherein the plurality of outer lumens have equal diameters when inflated by an inflation medium.
- 21. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 1, wherein the plurality of outer lumens have unequal diameters when inflated by the inflation medium.

09/506,081 Page 5 of 36 3764.P025

- 22. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 9, wherein the balloon treatment area has a longitudinal length in a range of approximately 10-250 mm.
- 23. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 9, wherein the balloon treatment area has a longitudinal length in a range of approximately 18-54 mm.
- 24. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 9, wherein the balloon treatment area has a combined diameter in a range of approximately 1.5-10 mm when inflated by the inflation medium.
- 25. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 9, wherein the balloon treatment area has a combined diameter in a range of approximately 1.5-4 mm when inflated by the inflation medium.
- 26. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 1, wherein the multi-lumen balloon is manufactured from a material selected from the group consisting of resin, nylon and pebax.
- 27. (Currently Amended) A multi-lumen balloon radiation centering catheter assembly, comprising:

09/506,081 Page 6 of 36 3764.P025

- a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen, the plurality of outer lumens integrally coupled with the central lumen so as to form the multi-lumen balloon with a continuous perimeter; and
- a catheter shaft disposed proximate to the balloon, the catheter shaft including an inner lumen longitudinally extending through at least a portion of the catheter shaft proximate the balloon and connected to the central lumen, the inner lumen adapted for receiving a radiation source lumen, the inner lumen further adapted for receiving a guidewire lumen for positioning the multi-lumen balloon radiation centering catheter within a body vessel, wherein the guidewire lumen is positioned distal to the multi-lumen balloon, and wherein slideable seals are provided to seal both ends of the catheter shaft where a guidewire is received.
- 28. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 27, wherein the inner lumen is further adapted for receiving a plurality of inflation lumens that are in fluid communication with the plurality of outer lumens to allow an inflation medium to enter and inflate the plurality of outer lumens so as to cause the radiation source lumen to be centered within a body vessel.
- 29. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 28, wherein each outer lumen is inflatable to different inflation pressures.
- 30. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 27, wherein the inner lumen serves as an inflation lumen for the plurality of outer lumens.

09/506,081 Page 7 of 36 3764.P025

- 31. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 27, further comprising a catheter outer member coupled with the catheter shaft.
- 32. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 31, wherein the catheter outer member includes an outer member lumen extending through at least a portion of the catheter outer member and connected to the catheter shaft inner lumen, the outer member lumen adapted for receiving a inflation lumen that is in fluid communication with the plurality of outer lumens for inflating the multi-lumen balloon.
- 33. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 27, wherein the radiation source lumen extends lengthwise through the central lumen of the multi-lumen balloon.
- 34. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 33, wherein the plurality of outer lumens have a plurality of proximal ends and distal ends coupled with the radiation source lumen so as to form a balloon proximal seal and a balloon distal seal.
- 35. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 34, wherein a balloon treatment area is formed between the balloon proximal seal and the balloon distal seal.

09/506,081 Page 8 of 36 3764.P025

- 36. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 35, wherein the balloon treatment area has a fluted shape.
- 37. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 27, wherein the guidewire lumen is a tip rapid exchange guidewire lumen.
- 38. (Original) The multi-lumen balloon radiation centering catheter of claim assembly 27, further comprising a soft tip coupled to a distal end of the guidewire lumen.
- 39 (Original) The multi-lumen balloon radiation centering catheter of claim assembly 34, further comprising a distal marker and a proximal marker coupled with the radiation source lumen and disposed within the balloon distal seal and the balloon proximal seal.
- 40. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 39, wherein the distal marker is part of a radiation source lumen plug.
- 41. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 27, further comprising a radiation source disposed within the radiation source lumen.
- 42. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 41, wherein the radiation source comprises a gamma radiation-emitting radiation source.

09/506,081 Page 9 of 36 3764.P025

- 43. (Original) The multi-lumen balloon radiation centering catheter assembly of claim41, wherein the radiation source comprises a beta radiation-emitting radiation source.
- 44. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 43, wherein the radiation source comprises phosphorous-32.
- 45. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 28, wherein when inflated and engaged with the body vessel, the plurality of outer lumens form straight longitudinal paths that allow for perfusion of blood past the multi-lumen balloon.
- 46. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 27, wherein the plurality of outer lumens have equal diameters when inflated by an inflation medium.
- 47. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 27, wherein the plurality of outer lumens have unequal diameters when inflated by an inflation medium.
- 48. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 35, wherein the balloon treatment area has a longitudinal length in a range of approximately 10-250 mm.

- 49. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 35, wherein the balloon treatment area has a longitudinal length in a range of approximately 18-54 mm.
- 50. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 35, wherein the balloon treatment area has a combined diameter in a range of approximately 1.5-10 mm when inflated by the inflation medium.
- 51. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 35, wherein the balloon treatment area has a combined diameter in a range of approximately 1.5-4 mm when inflated by the inflation medium.
- 52. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 27, wherein the multi-lumen balloon is manufactured from a material selected from the group consisting of resin, nylon and Pebax.
- 53. (Currently Amended) The multi-lumen balloon radiation centering catheter assembly of claim [[3]] 28, wherein the outer lumens are inflated at different inflation pressures to cause the central lumen not to be centered within the body vessel.
- 54. (Withdrawn) A multi-lumen balloon radiation centering catheter assembly, comprising:

09/506,081 Page 11 of 36 3764.P025

- a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen, the plurality of outer lumens integrally coupled with the central lumen so as to form the multi-lumen balloon having a proximal seal end and a distal seal end, the balloon further comprising a plurality of bores communicating between the central lumen and the plurality of outer lumens; and
- a catheter shaft having a proximal end and a distal end, the catheter shaft distal end coupled with the balloon proximal seal end, the catheter shaft comprising an inner tubular member which extends coaxially within an outer tubular member, the inner tubular member adapted for receiving a radiation source lumen, the inner tubular member further adapted for receiving at least one inflation lumen that is in fluid communication with the plurality of outer lumens to allow an inflation medium to inflate the plurality of outer lumens so as to cause the radiation source lumen to be centered within a body vessel.
- 55. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 54, wherein the inner tubular member is further adapted to receive a guidewire lumen for positioning the multi-lumen balloon radiation centering catheter assembly within the body vessel.
- 56. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 55, wherein the guidewire lumen extends lengthwise through the central lumen.

09/506,081 Page 12 of 36 3764.P025

- 57. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 54, wherein the inner tubular member extends lengthwise through the central lumen.
- 58. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 57, wherein the plurality of outer lumens have a plurality of proximal and distal ends coupled with the inner tubular member so as to form a fluted shape multi-lumen balloon between the balloon distal seal end and balloon proximal seal end.
- 59. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 57, wherein the inner tubular member extending lengthwise through the central lumen of the multi-lumen balloon is adapted to be attached with a tip rapid exchange guidewire lumen for positioning the catheter within the body vessel.
- 60. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 55, further comprising a soft tip coupled to a distal end of the guidewire lumen.
- 61. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 59, further comprising a soft tip coupled to a distal end of the tip rapid exchange guidewire lumen.
- 62. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 54, further comprising a distal marker and a proximal marker coupled with the

09/506,081 Page 13 of 36 3764.P025

radiation source lumen and disposed within the distal seal end and the proximal seal end of the multi-lumen balloon.

- 63. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 62, wherein the distal marker is part of a radiation source lumen plug.
- 64. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 54, further comprising a radiation source disposed within the radiation source lumen.
- 65. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 64, wherein the radiation source comprises a gamma radiation-emitting radiation source.
- 66. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 64, wherein the radiation source comprises a beta radiation-emitting radiation source.
- 67. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 66, wherein the radiation source comprises phosphorous-32.
- 68. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 54, wherein when inflated and engaged with the body vessel, the plurality of outer lumens form straight longitudinal paths that allow for perfusion of blood past the multi-lumen balloon.

09/506,081 Page 14 of 36 3764.P025

- 69. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 54, wherein a balloon treatment area is formed between the balloon distal seal end and the balloon proximal seal end.
- 70. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 54, wherein the plurality of outer lumens have equal diameters when inflated by the inflation medium.
- 71. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 54, wherein the plurality of outer lumens have unequal diameters when inflated by the inflation medium.
- 72. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 54, wherein the catheter shaft is a standard rapid exchange type.
- 73. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 54, wherein the catheter shaft is a tip rapid exchange type.
- 74. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 54, wherein the catheter shaft is an over-the-wire catheter type.

- 75. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 69, wherein the balloon treatment area has a longitudinal length in a range of approximately 10-250 mm.
- 76. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 69, wherein the balloon treatment area has a longitudinal length in a range of approximately 18-54 mm.
- 77. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 69, wherein the balloon treatment area has a combined diameter in a range of approximately 1.5-10 mm when inflated by the inflation medium.
- 78. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 69, wherein the balloon treatment area has a combined diameter in a range of approximately 1.5-4 mm when inflated by the inflation medium.
- 79. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 54, wherein the multi-lumen balloon is manufactured from a material selected from the group consisting of resin, nylon and pebax.
- 80. (Currently Amended) A multi-lumen balloon radiation centering catheter assembly, comprising:
- a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen, the plurality of outer lumens integrally coupled with the central lumen

09/506,081 Page 16 of 36 3764.P025

so as to form the multi-lumen balloon with a continuous perimeter and having a slideable proximal seal end and a distal seal end to seal a lumen capable of receiving a guidewire; and

- a catheter shaft having a proximal end and a distal end, the catheter distal end coupled with the balloon proximal seal end, the catheter shaft comprising an inner tubular member which extends coaxially within an outer tubular member, the inner tubular member adapted for receiving a radiation source lumen, the inner tubular member further adapted for receiving at least one inflation lumen that is in fluid communication with the plurality of outer lumens to allow an inflation medium to inflate the plurality of outer lumens so as to cause the radiation source lumen to be centered within a body vessel.
- 81. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 80, wherein the inner tubular member is further adapted to receive a guidewire lumen for positioning the multi-lumen balloon radiation centering catheter assembly within the body vessel.
- 82. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 81, wherein the guidewire lumen extends lengthwise through the central lumen.
- 83. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 80, wherein the inner tubular member extends lengthwise through the central lumen.

09/506,081 Page 17 of 36 3764.P025

- 84. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 83, wherein the plurality of outer lumens have a plurality of proximal and distal ends coupled with the inner tubular member so as to form a fluted shape multi-lumen balloon between the balloon distal seal end and balloon proximal seal end.
- 85. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 83, wherein the inner tubular member extending lengthwise through the central lumen of the multi-lumen balloon is adapted to be attached with a tip rapid exchange guidewire lumen for positioning the catheter within the body vessel.
- 86. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 81, further comprising a soft tip coupled to a distal end of the guidewire lumen.
- 87. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 85, further comprising a soft tip coupled to a distal end of the tip rapid exchange guidewire lumen.
- 88. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 80, further comprising a distal marker and a proximal marker coupled with the radiation source lumen and disposed within the distal seal end and the proximal seal end of the multi-lumen balloon.

09/506,081 Page 18 of 36 3764.P025

- 89. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 88, wherein the distal marker is part of a radiation source lumen plug.
- 90. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 80, further comprising a radiation source disposed within the radiation source lumen.
- 91. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 90, wherein the radiation source comprises a gamma radiation-emitting radiation source.
- 92. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 90, wherein the radiation source comprises a beta radiation-emitting radiation source.
- 93. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 92, wherein the radiation source comprises phosphorous-32.
- 94. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 80, wherein when inflated and engaged with the body vessel, the plurality of outer lumens form straight longitudinal paths that allow for perfusion of blood past the multi-lumen balloon.
- 95. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 80, wherein a balloon treatment area is formed between the balloon distal seal end and the balloon proximal seal end.

09/506,081 Page 19 of 36 3764,P025

- 96. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 80, wherein the plurality of outer lumens have equal diameters when inflated by the inflation medium.
- 97. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 80, wherein the plurality of outer lumens have unequal diameters when inflated by the inflation medium.
- 98. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 80, wherein the catheter shaft is a standard rapid exchange type.
- 99. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 80, wherein the catheter shaft is a tip rapid exchange type.
- 100. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 80, wherein the catheter shaft is an over-the-wire catheter type.
- 101. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 95, wherein the balloon treatment area has a longitudinal length in a range of approximately 10-250 mm.

- 102. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 95, wherein the balloon treatment area has a longitudinal length in a range of approximately 18-54 mm.
- 103. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 95, wherein the balloon treatment area has a combined diameter in a range of approximately 1.5-10 mm when inflated by the inflation medium.
- 104. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 95, wherein the balloon treatment area has a combined diameter in a range of approximately 1.5-4 mm when inflated by the inflation medium.
- 105. (Original) The multi-lumen balloon radiation centering catheter assembly of claim 95, wherein the multi-lumen balloon is manufactured from a material selected from the group consisting of resin, nylon and pebax.
- 106. (Withdrawn) A multi-lumen balloon radiation centering catheter assembly, comprising:
- a catheter shaft having a distal end and a proximal end, the catheter shaft comprising an inner tubular member extending lengthwise through an outer tubular member, the inner tubular member adapted for receiving a radiation source lumen for centering of the radiation source within a body vessel; and

09/506,081 Page 21 of 36 3764.P025

- means for substantially centering the radiation source lumen radially within the body vessel, the centering means disposed at the catheter distal end and comprising a multi-lumen balloon having a plurality of outer lumens disposed around a central lumen, the plurality of outer lumens integrally coupled with the central lumen, the multi-lumen balloon further comprising a plurality of bores communicating between the central lumen and the plurality of outer lumens to allow an inflation medium to enter and inflate the plurality of outer lumens so as to cause the radiation source lumen to be centered within a body vessel.
- 107. (Withdrawn) A multi-lumen balloon radiation centering catheter assembly, comprising:
- a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen, the plurality of outer lumens integrally coupled with the central lumen so as to form the multi-lumen balloon having a proximal seal end and a distal seal end, the balloon further comprising a plurality of bores communicating between the central lumen and the plurality of outer lumens; and
- an over-the-wire catheter shaft having a proximal end and a distal end, the over-the-wire catheter distal end coupled with the balloon proximal seal end, the over-the-wire catheter shaft comprising an inner tubular member which extends coaxially within an outer tubular member, the inner tubular member adapted for receiving a radiation source lumen, the inner tubular member further adapted for receiving at least one inflation lumen that is in fluid communication with the plurality of outer lumens to allow an

inflation medium to inflate the plurality of outer lumens so as to cause the radiation source lumen to be centered within a body vessel.

- 108. (Withdrawn) A multi-lumen balloon radiation centering catheter assembly, comprising:
- a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen, the plurality of outer lumens integrally coupled with the central lumen so as to form the multi-lumen balloon having a proximal seal end and a distal seal end, the balloon further comprising a plurality of bores communicating between the central lumen and the plurality of outer lumens; and
- a standard rapid exchange catheter shaft having a proximal end and a distal end, the standard rapid exchange catheter distal end coupled with the balloon proximal seal end, the standard rapid exchange catheter shaft comprising an inner tubular member which extends coaxially within an outer tubular member, the inner tubular member adapted for receiving a radiation source lumen, the inner tubular member further adapted for receiving at least one inflation lumen that is in fluid communication with the plurality of outer lumens to allow an inflation medium to inflate the plurality of outer lumens so as to cause the radiation source lumen to be centered within a body vessel.
- 109. (Withdrawn) A multi-lumen balloon radiation centering catheter assembly, comprising:
- a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen, the plurality of outer lumens integrally coupled with the central lumen

09/506,081 Page 23 of 36 3764.P025

so as to form the multi-lumen balloon having a proximal seal end and a distal seal end, the balloon further comprising a plurality of bores communicating between the central lumen and the plurality of outer lumens; and

- a tip rapid exchange catheter shaft having a proximal end and a distal end, the tip rapid exchange catheter distal end coupled with the balloon proximal seal end, the tip rapid exchange catheter shaft comprising an inner tubular member which extends coaxially within an outer tubular member, the inner tubular member adapted for receiving a radiation source lumen, the inner tubular member further adapted for receiving at least one inflation lumen that is in fluid communication with the plurality of outer lumens to allow an inflation medium to inflate the plurality of outer lumens so as to cause the radiation source lumen to be centered within a body vessel.
- 110. (Withdrawn) A multi-lumen balloon radiation centering catheter assembly, comprising:
- a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen, the plurality of outer lumens integrally coupled with the central lumen so as to form the multi-lumen balloon having a slideable proximal seal and a slideable distal seal, the balloon further comprising a plurality of bores communicating between the central lumen and the plurality of outer lumens; and

a catheter shaft having a proximal end and a distal end, the catheter distal end coupled with the balloon slideable proximal seal, the catheter shaft comprising an inner tubular member which extends coaxially within an outer tubular member, the inner tubular member adapted for receiving a radiation source lumen, the inner tubular member further adapted for

receiving at least one inflation lumen that is in fluid communication with the plurality of outer lumens to allow an inflation medium to inflate the plurality of outer lumens so as to cause the radiation source lumen to be centered within a body vessel.

- 111. (Withdrawn) A multi-lumen balloon radiation centering catheter assembly, comprising:
- a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen, the outer lumens integrally coupled with the central lumen so as to form the multi-lumen balloon;
- a catheter shaft disposed proximate to the balloon, the catheter shaft including an inner lumen longitudinally extending through at least a portion of the catheter shaft proximate the balloon, the inner lumen adapted for receiving a radiation source lumen, the inner lumen further adapted to receive a guidewire for positioning the multi-lumen balloon radiation centering catheter within a body vessel; and
- a slideable distal seal disposed distal to the multi-lumen balloon and a slideable proximal seal disposed proximate to the multi-lumen balloon.
- 112. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 111, wherein the inner lumen is further adapted for receiving at least one inflation lumen that is in fluid communication with the outer balloon lumens to allow an inflation medium to enter and inflate the outer lumens so as to cause the radiation source lumen to be centered within a body vessel.

09/506,081 Page 25 of 36 3764.P025

- 113. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 111, wherein the guidewire lumen is adapted for receiving a guidewire having a guidewire outer diameter, wherein the guidewire extends lengthwise through one of the plurality of outer lumens of the multi-lumen balloon.
- 114. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 113, wherein the slideable proximal and distal seals have an inner diameter formed between the multi-lumen balloon and the catheter shaft.
- 115. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 114, wherein the guidewire outer diameter is approximately equal to the inner diameter of the slideable proximal and distal seals.
- 116. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 111, wherein the radiation source lumen extends lengthwise through the central lumen of the multi-lumen balloon.
- 117. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 113, wherein the guidewire is a standard rapid exchange guidewire.
- 118. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 112, wherein the slideable distal and proximal seals are formed such that the

09/506,081 Page 26 of 36 3764.P025

guidewire rotates and axially slides relative to the catheter shaft while maintaining the inflation medium within the multi-lumen balloon radiation centering catheter assembly.

- (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 111, further comprising a distal marker and a proximal marker coupled with the radiation source lumen and disposed within a distal seal end and a proximal seal end of the multi-lumen balloon.
- 120. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 119, wherein the distal marker is part of a source lumen plug.
- 121. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 111, wherein the radiation source lumen is adapted for receiving a radiation source.
- 122. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 121, wherein the radiation source comprises a gamma radiation-emitting radiation source.
- 123. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 121, wherein the radiation source comprises a beta radiation-emitting radiation source.
- 124. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 123, wherein the radiation source comprises phosphorous-32.

09/506,081 Page 27 of 36 3764.P025

- 125. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 111, wherein when inflated and engaged with the body vessel, the plurality of outer lumens form straight longitudinal paths that allow for perfusion of blood past the multi-lumen balloon.
- 126. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 119, wherein a balloon treatment area is formed between the balloon distal seal end and the balloon proximal seal end.
- 127. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 111, wherein the plurality of outer lumens have equal diameters when inflated by an inflation medium.
- 128. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 111, wherein the plurality of outer lumen have unequal diameters when inflated by an inflation medium.
- 129. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 126, wherein the balloon treatment area has a longitudinal length in a range of approximately 10-250 mm.

09/506,081 Page 28 of 36 3764.P025

- 130. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 126, wherein the balloon treatment area has a longitudinal length in a range of approximately 18-54 mm.
- 131. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 126, wherein the balloon treatment area has a combined diameter in a range of approximately 1.5-10 mm when inflated by an inflation medium.
- 132. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 126, wherein the balloon treatment area has a combined diameter in a range of approximately 1.5-4 mm when inflated by an inflation medium.
- 133. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 113, wherein the slideable distal and proximal seals further include a hydrogel material disposed between the guidewire and the slideable distal and proximal seals.
- 134. (Withdrawn) The multi-lumen balloon radiation centering catheter assembly of claim 113, wherein the slideable distal and proximal seals further include an O-ring disposed between the guidewire and the slideable distal and proximal seals.
- 135. (Withdrawn) A multi-lumen balloon radiation centering catheter assembly, comprising:

09/506,081 Page 29 of 36 3764.P025

- a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen, the plurality of outer lumens integrally coupled with the central lumen so as to form the multi-lumen balloon; and
- a catheter shaft disposed proximate to the balloon, the catheter shaft having at least two guidewire exit notches, the catheter shaft further including an inner lumen longitudinally extending through at least a portion of the catheter shaft proximate the balloon and connected to the central lumen, the inner lumen adapted for receiving a radiation source lumen, the inner lumen further adapted for receiving a guidewire for positioning the multi-lumen balloon radiation centering catheter within a body vessel, wherein the guidewire extends lengthwise outside the multi-lumen balloon.

136. (Withdrawn) A multi-lumen balloon radiation centering catheter assembly, comprising:

- a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen, the plurality of outer lumens integrally coupled with the central lumen so as to form the multi-lumen balloon;
- at least one marker attached to the multi-lumen balloon; and
- a catheter shaft disposed proximate to the balloon, the catheter shaft including an inner lumen longitudinally extending through at least a portion of the catheter shaft proximate the balloon and connected to the central lumen, the inner lumen adapted for receiving a radiation source lumen, the inner lumen further adapted for receiving a guidewire lumen for positioning the multi-lumen balloon radiation centering catheter within a body vessel.

- 137. (Withdrawn) A multi-lumen balloon radiation centering catheter assembly, comprising:
- a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen, the plurality of outer lumens integrally coupled with the central lumen so as to form the multi-lumen balloon;
- at least one marker attached to the multi-lumen balloon using a vapor deposition process; and
- a catheter shaft disposed proximate to the balloon, the catheter shaft including an inner lumen longitudinally extending through at least a portion of the catheter shaft proximate the balloon and connected to the central lumen, the inner lumen adapted for receiving a radiation source lumen, the inner lumen further adapted for receiving a guidewire lumen for positioning the multi-lumen balloon radiation centering catheter within a body vessel.

138. (Withdrawn) A balloon catheter assembly comprising:

a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen; and

a catheter shaft disposed proximate to the multi-lumen balloon and coupled to the multi-lumen balloon, the catheter shaft including a shaft inner lumen through at least a portion of the catheter shaft proximate the multi-lumen balloon and coupled to the central lumen, the shaft inner lumen to receive a plurality of inflation lumens that are in fluid coupling with the plurality of inflatable outer lumens to allow an inflation medium to enter

the plurality of inflatable outer lumens and independently inflate at least one inflatable outer lumen to position the central lumen of the multi-lumen balloon.

- 139. (Withdrawn) The balloon catheter assembly of claim 138, wherein at least one inflatable outer lumen is kept in a deflated configuration when the balloon catheter assembly is deployed within a body vessel.
- 140. (Withdrawn) A method of manufacture of a balloon catheter assembly, the method comprising:

providing a multi-lumen balloon having a plurality of inflatable outer lumens disposed around a central lumen; and

coupling a catheter shaft to the multi-lumen balloon, the catheter shaft disposed proximate to the multi-lumen balloon, the catheter shaft having a shaft inner lumen through at least a portion of the catheter shaft proximate the multi-lumen balloon and coupled to the central lumen, the shaft inner lumen to receive a plurality of inflation lumens that are in fluid coupling with the plurality of inflatable outer lumens to allow an inflation medium to enter the plurality of inflatable outer lumens and independently inflate at least one inflatable outer lumen to position the central lumen of the multi-lumen balloon.

141. (Withdrawn) A method of centering a lumen within a body vessel of a patient, the method comprising:

providing a multi-lumen balloon catheter assembly comprising a multi-lumen balloon with a plurality of inflatable outer lumens disposed around a central lumen and a

09/506,081 Page 32 of 36 3764.P025

catheter shaft disposed proximate to the multi-lumen balloon, wherein the catheter shaft comprises a shaft inner lumen through at least a portion of the catheter shaft proximate the multi-lumen balloon and coupled to the central lumen, the shaft inner lumen to receive a plurality of inflation lumens that are in fluid coupling with the plurality of inflatable outer lumens;

inserting the multi-lumen balloon catheter assembly into a body vessel lumen and advancing the balloon catheter to a desired region of the body vessel, the desired region of the body vessel having an eccentric residual plaque therein that causes the body vessel lumen to be off center relative to an arterial structure of the body vessel; and

inflating at least one inflatable outer lumen of the multi-lumen balloon using an inflation medium to center the central lumen relative to the arterial structure of the body vessel.

142. (Withdrawn) The method of claim 141, wherein at least one of the plurality of inflatable outer lumens is kept in a deflated configuration when the multi-lumen balloon catheter assembly is deployed within the body vessel of the patient.